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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

10/576,528

04/19/2006

Kirk Matthew Schnorr

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NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER

HIBBERT, CATHERINE S

ART UNIT

PAPER NUMBER

1636

NOTIFICATION DATE

DELIVERY MODE

12/01/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/576,528 | Applicant(s) SCHNORR ET AL. | |
| | Examiner CATHERINE HIBBERT | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-76 is/are pending in the application.
- 4a) Of the above claim(s) 60-62 and 74-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-59 and 63-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's submission filed 11 September 2009 is received and entered.

Applicant's Amendment to the Claims and Amendment to the Specification filed 26 May 2009 is received and entered. This Application US 10/576,528, filed 19 April 2006, is a National Phase entry of PCT/DK2004/000734, filed 26 October 2004, which claims benefit of US Provisional 60/515,927, filed 30 October 2003, and claims Foreign Priority to Denmark Patent Application 2003 01607, filed 30 October 2003.

Claims 1-47 are cancelled. Claims 48-76 are new. Claims 48-76 are pending. Claims 60-62 and 74-76 are withdrawn as directed to non-elected subject matter. Claims 48-59 and 63-73 are under examination in this action.

Election/Restrictions

Newly submitted claims 60-62 and 74-76 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 60-62 and 74-76 are *methods* of using the carbohydrate-binding module but the elected invention is drawn to a carbohydrate-binding module *product*. The product and process claims are properly considered distinct inventions because it has been determined that the inventions lack unity of invention. The inventions listed as Groups I-IV lack the same or corresponding "special technical feature" because the common technical feature that unifies the invention groups is not considered a "special technical feature" because the technical feature of the instant claims, as written, does not make a contribution over the prior art. For example, it was determined in the restriction

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requirement and the previous office action that the carbohydrate-binding domain, as broadly claimed, does not represent an advance over the art (see Levy et al, "Cellulose-binding domains--Biotechnological applications", cited in search report) and hence there is no unity of invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 60-62 and 74-76 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicants response in the REMARKS filed 26 May 2009 is to traverse both restriction requirements. Applicants argue that the Office states in the previous action that:

"[t]he phrase 'an amino acid sequence' reads broadly on any dipeptide of the sequence having 50% identity to the sequence 34-174 of SEQ ID NO: 2." This is not a reasonable interpretation of the claims, and contrary to how this phrase would be interpreted by persons skilled in the art. Under the Office's interpretation, almost all sequences are 100% identical.

Moreover, Applicants argue:

the Office's interpretation is not consistent with the specification. The specification describes at pages 6 and 7 how to determine % identity between two amino acid sequences. For example, it discloses that FIG2 of *Saccharomyces cerevisiae* (Swiss-Prt No. p25653) (a copy of which is attached hereto) is 28.7% identical to the sequence of amino acids 34- 174 of SEQ ID NO: 2. Under the Office's interpretation, these two sequences would be 100% identical because FIG2 comprises the amino acids Val-Val at positions 13-14 which are identical to the amino acids at positions 58-59 of SEQ ID NO: 2.

In addition, Applicants argue:

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The Office provides no evidence that the carbohydrate-binding modules disclosed in Levy et al. have an amino acid sequence which is at least 80% identical to the sequence of amino acids 34-174 of SEQ ID NO: 2. As described in the specification, the carbohydrate-binding module (see page 3, lines 9-10) from *Pseudoplectania nigrella* is "the first known member of a new family of CBM's" (see page 3, lines 9-10). Thus, the carbohydrate-binding modules described in Levy et al do not have an amino sequence which is homologous to the sequence of amino acids 34-174 of SEQ ID NO: 2.

Applicants traverse is not found persuasive for reasons of record as restated above. Particularly, Applicants argument that the claims construction is not correct because Applicants argue that the claim interpretation is overly broad regarding claim language drawn to, for example, "a polypeptide having a sequence which has at least 90% identity with the sequence of amino acids 34-174 of SEQ ID NO:2" which Examiner interprets as a polypeptide having "a sequence", such as any di-peptide, or tri-peptide sequence, which has at least 90% identity found within the sequence of amino acids 34-174 of SEQ ID NO:2, is not persuasive because claims must be given their broadest reasonable interpretation during examination in light of the instant specification.

Response to Amendment/Arguments

Any objections/rejections not repeated herein are withdrawn.

Any objections/rejections to cancelled claims 29-39, 43 and 44 are moot.

New grounds of objection/rejection necessitated by amendment

Claim Objections

Newly added Claims 52 and 53 are objected to because of the following informalities: The claims are missing a verb. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly added Claims 48-59 and 63-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 recites the limitation "the polypeptide" in line 9. There is insufficient antecedent basis for this limitation in the claim because it is unclear whether "the polypeptide" is referring to each recitation of "a polypeptide" in steps (a) to (c) collectively or individually or in the alternative. Therefore, one of ordinary skill in the art would not be able to determine the metes and bounds of applicant's invention.

Additionally, Claims 48, 52, 53, 68 and 69 recite the terms "under high stringency conditions" and/or "under very high stringency conditions". The terms "high" and "very high" in claims 48, 52, 53, 68 and 69 are relative terms which renders the claims indefinite. The term "high" and "very high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 49-59 and 63-73 are additionally indefinite insofar as they depend from Claims 48, 52 and 53.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Newly added Claims 48-59 and 63-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by claim amendments, however Applicants response to the previous rejection under written description is addressed below.**

See MPEP § 2163, for example, for written description information which is relevant to the below discussion.

In the instant case, the claims are drawn to a genus of isolated carbohydrate-binding modules having carbohydrate-binding module activity, the modules selected from the group consisting of: (a) a polypeptide having a sequence which has at least 90% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2; (b) a polypeptide encoded by a DNA sequence that hybridizes to the DNA sequence of nucleotides 109-531 of SEQ ID NO: 1 under high stringency conditions; and (c) a polypeptide which is a fragment of the sequence of amino acids 34-174 of SEQ ID NO: 2, wherein the polypeptide has carbohydrate-binding module activity.

Initially it is noted that claims must be given their broadest reasonable interpretation in light of the instant specification during examination. Therefore, it is

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noted that the base Claim 48 reads on an isolated carbohydrate-binding module which is “a polypeptide” comprising “a sequence” which has at least 90% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2. It is noted that an amino acid sequence that is the dipeptide glycine-glycine, or serine-serine, or alanine-valine, for example, would each read on a sequence which has at least 100% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 48-59 are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are numerous to any polypeptide which is a fragment of the sequence of amino acids 34-174 of SEQ ID NO:2. In addition, the dependent Claims 49-59 do not remedy the written description requirement because they also claim the carbohydrate-binding module of Claim 48.

Specifically, the claims lack written description because although one of ordinary skill in the art could reasonably predict the amino acid sequence (structure) of a given polypeptide that was a fragment of SEQ ID NO: 2 or that had a given % identity to the known SEQ ID NO: 2 and also could reasonably predict a polypeptide structure encoded by a DNA sequence having identity with the nucleotide sequence 109-531 of SEQ ID NO: 1, it is clear that experimentation would be required to determine whether any of these given polypeptide sequences would meet the functional requirement “wherein the polypeptide has carbohydrate-binding module activity”. For example, the

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instant specification recites on page 2, lines 20-23: "It is contemplated that new CBD's can be found by cloning cellulase, xylanases or other plant cell wall degrading enzymes and measure the binding to e.g. cellulose. If the enzyme activity is bound to Avicel under the standard conditions described below, it can be assumed that part of the gene codes for a binding domain". Therefore, one of ordinary skill in the art would not be able to determine which of the species of carbohydrate-binding module sequences would have carbohydrate-binding module activity without experimentation and thus the structure-function correlation is considered to be unpredictable. In addition, regarding Claim 48, the limitation directed to "a polypeptide encoded by a DNA sequence that hybridizes to the DNA sequence of nucleotides 109-531 of SEQ ID NO:1 under high stringency conditions" lacks written description because the *structure* requirement for this limitation as well as the functional requirement is unpredictable.

Although the claims recite some functional characteristics, the claims lack written description because there is no disclosure of a *correlation* between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus. While having written description of SEQ ID NO: 1, the nucleotide sequence 109-531 of SEQ ID NO:1, and SEQ ID NO: 2 and the amino acid sequence 34-174 of SEQ ID NO: 2, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims. For example, the specification does not provide a representative number of examples of sequences that have at least 95% identity with or are fragments of the sequence of

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amino acids 34-174 of SEQ ID NO: 2 such that one of ordinary skill in the art would be able to envision the next species of the genus of polypeptides that have carbohydrate-binding module activity.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Applicants response is to traverse the rejection and to cancel the rejected claims. Since Applicants have cancelled Claims 29-39 and 43-44, Applicants traverse of the rejection of Claims 29-39 and 43-44 under 35 U.S.C. 112, Written Description, is rendered moot. However, Applicants arguments are addressed below insofar as they may be applicable to newly added claims rejected herein under 35 U.S.C. 112, Written Description. Applicants argue in REMARKS filed 5/26/2009 that:

the Written Description Training Materials published by the USPTO on March 25, 2008 provides guidance in applying the written description requirement. Particularly relevant to the instant application is Example 11, "Percent Identity" and more specifically, Example 11B "Art-Recognized Structure-Function Correlation Present." Example 11B provides "Claim 2" which is a claim to an isolated nucleic acid sequence that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2; wherein the polypeptide has activity Y. The specification of Example 11B discloses the reduction to practice of

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only a single species that encodes SEQ ID NO: 2 and has activity Y, i.e., nucleic acid SEQ ID NO: 1, but the specification does not teach which 15% of the amino acids will vary from SEQ ID NO: 2, nor any other polypeptides with 85% identity to SEQ ID NO: 2 that have activity Y. However, the knowledge in the art of the genetic code would allow one skilled in the art, with the aid of a computer, to list all of the nucleotide sequences capable of encoding a polypeptide with at least 85% identity to SEQ ID NO: 2, thus identifying all polypeptides having at least 85% identity to SEQ ID NO: 2. Further, Example 11B provides that the specification identifies two domains responsible for the activity Y, i.e., a binding domain and a catalytic domain, and predicts that conservative mutations in these domains will result in the protein having activity Y, and those of ordinary skill in the art would expect that many of the conservative substitutions would result in a protein having the required activity. Additionally, substitutions outside of the functional domains were predicted to have little effect on activity Y. Thus, a correlation exists between the function of the claimed protein and the structure of the disclosed binding and catalytic domains. The conclusion is that the written description requirement is satisfied for Claim 2 of Example 11B.

Applicants further submit that “the claims of the instant application comply with the written description requirement under 35 U.S.C. 112, first paragraph”. Specifically, Applicants argue that the “claimed invention is directed to carbohydrate-binding modules, which (a) have a sequence which has at least 90% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2; (b) are encoded by a DNA sequence that hybridizes to the DNA sequence of nucleotides 109-531 of SEQ ID NO: 1 under high stringency conditions; or (c) are a fragment of the sequence of amino acids 34-174 of SEQ ID NO: 2. Thus, the claimed polypeptides are structurally similar.” Furthermore, Applicants argue:

It would be routine for persons of ordinary skill in the art to identify each amino acid sequence which falls within the 90% sequence identity recitation and to test the polypeptide for carbohydrate-binding module activity. The specification discloses a computer program for determining percent identity at pages 6 and 7. Furthermore, carbohydrate-binding modules are well characterized and those skilled in the art can recognize the conserved regions among carbohydrate-binding modules. Just as one skilled in the art can recognize mutations to the catalytic and binding domains and substitutions outside of the catalytic and

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binding domains of SEQ ID NO: 2 in Example 11B which would result in a polypeptide having activity Y, persons skilled in the art also can recognize mutations to the polypeptide of SEQ ID NO: 2, which would result in a polypeptide having carbohydrate-binding module activity. Applicants respectfully submit that the claims of the instant application meet the requirement for written description under 35 U.S.C. 112, first paragraph, by disclosing relevant, identifying characteristics, e.g., the structure of SEQ ID NO: 2, and by functional characteristics, i.e., carbohydrate-binding module activity, coupled with the known correlation between function and structure. Given the high degree of identity recited in the claims, a high degree of predictability exists as to the structure and function of polypeptide falling within the claims. Moreover, it is well established in the art that the definition of a genus of genes encoding polypeptides having an enzyme activity of interest is accomplished by using structural features that show the relatedness of the genes and their encoded products. For decades the scientific community has employed three structural features to define the relatedness of genes and their products. The three structural features are (1) percent identity of the amino acid sequences encoded by the genes, (2) percent homology of the nucleic acid sequences of the genes, and (3) nucleic acid hybridizations under defined stringent conditions to identify complementary strands of genes encoding the same or similar enzyme or protein function. These structural features have been used to predict the function of polypeptides encoded by novel genes, and to place them in an existing genus.

These structural features are highly predictive of protein function. In particular, proteins that share 80% amino acid identity are known to possess the same catalytic/biochemical function. In fact, 80% identity is a conservative criterion for judging functional similarity. A long history of structure-function studies has demonstrated that single domain proteins that share substantial similarity (and >30% identity) over their entire length (>80 residues) without introduction of numerous gaps are almost certainly homologous (derive from a common evolutionary ancestor) and share the same three-dimensional structure (see Marti-Renom et al., 2000, *Annu. Rev. Biophys. Biomol. Struct.* 29:291-325 (a copy of which is attached hereto)). At the 80-90% level of amino acid identity, orthologous enzymes in related species are virtually guaranteed to share the same catalytic function and substrate specificity. A simple search of any public database using the criteria above for a reference protein of interest will prove that there is a definitive relationship between protein function and % identity at the amino acid level.

Moreover, Guo et al., 2004, *Proc. Nat. Acad. Sci. USA* 101:9205-9210 (a copy of which is attached hereto), observed that various residues of a protein are differentially sensitive to substitutions, and that tolerance of the entire protein to random change can be characterized by a probabilistic relationship termed the

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"x-factor." The x-factor is broadly defined as the probability that a random amino acid replacement will lead to functional inactivation. Moreover, they determined the x-factor to be 34% +/- 6%. Contrary to the Office's contention that random (even conservative) changes in a protein in the absence of structural information would adversely affect activity, the findings of Guo et al. support the contrary, i.e., that proteins are generally tolerant to random amino acid substitutions, and the probability of destroying protein function is small.

Makiewicz et al., 1994, J. Mol. Biol. 240:421-433 (a copy of which is attached hereto), examined 12 or 13 different amino acid substitutions at each residue across 90% of the 360 amino acid E. coli lac repressor protein. Reanalysis of their data by Guo et al. (2004) revealed an x-factor value of 34% which is identical to the value for random inactivation of human 3-methyladenine DNA glycosylase studied by Guo et al. Axe et al., 1998, Biochem. 37:7157-7166 (a copy of which is attached hereto), found that 95% of randomly introduced single amino acid substitutions did not lead to inactivated ribonuclease enzyme. Rennell et al., 1991, J. Mol. Biol. 222:67-88 (a copy of which is attached hereto), found that approximately 84% of amino acid substitutions in T4 lysozyme did not cause inactivation.

Applicants traverse is not found persuasive for reasons of record as restated above. Particularly, Applicants argument that the claims construction is not correct because Applicants argue that the claim interpretation is overly broad regarding claim language drawn to, for example, "a polypeptide having a sequence which has at least 90% identity with the sequence of amino acids 34-174 of SEQ ID NO:2" which Examiner interprets as a polypeptide having "a sequence", such as any di-peptide, or tri-peptide sequence, which has at least 90% identity found within the sequence of amino acids 34-174 of SEQ ID NO:2, is not persuasive because claims must be given their broadest reasonable interpretation during examination in light of the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Newly added Claims 48-58 and 63-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourne and Henrissat in “Glycoside hydrolases and glycosyltransferases: families and functional modules” (Current Opinion in Structural Biology, 2001, Vol. 11;pp 593-600, made of record in the IDS). **This is a new rejection necessitated by claim amendments, however Applicants response to the previous rejection under 102(b) as being anticipated by Bourne and Henrissat is addressed below.**

Initially it is noted that claims must be given their broadest reasonable interpretation in light of the instant specification during examination. Therefore, it is noted that the base Claim 48 reads on an isolated carbohydrate-binding module which is “a polypeptide” comprising “a sequence” which has at least 90% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2. It is noted that an amino acid sequence that is the dipeptide glycine-glycine, or serine-serine, or alanine-valine, for example, would each read on a sequence which has at least 100% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2.

In addition, Claims 63-73 are drawn to an enzyme hybrid comprising a carbohydrate-binding module of claim 48 and a catalytic domain exhibiting enzyme activity.

In addition, regarding Claims 56 and 72, the MPEP states that Product-By-Process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps” and further states that “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production” (MPEP 2113 [R-1]). Therefore, absent evidence to the contrary, the limitation of “a DNA sequence obtained from” *P. nigrella* CBS 444.97, in Claims 56 and 72, is not further limiting to the base claim 48.

Bourne and Henrissat teach many different carbohydrate-binding modules that are polypeptides comprising the dipeptide glycine-glycine, serine-serine, or alanine-valine and that are contained in (e.g. are in a composition with) cellulases and endoglucanases that read on enzyme hybrids comprising a carbohydrate-binding module and a catalytic domain exhibiting enzyme activity (e.g. page 593, Table 1 and page 597, Table 3). Bourne and Henrissat specifically teach isolated carbohydrate-binding modules (e.g. page 597, paragraph 3). In addition, one of ordinary skill in the art could reasonably interpret the carbohydrate-binding module contained in an isolated enzyme to read on an isolated carbohydrate-binding modules, especially in light of the description of a CBM in the instant specification (page 1, paragraph 2).

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Therefore, Bourne and Henrissat anticipate all the limitations of Claims 48-58 and 63-72.

Applicants response is to traverse the rejection and to cancel the rejected claims. Since Applicants have cancelled Claims 29-39 and 43-44, Applicants traverse of the rejection of Claims 29-39 and 43-44 under 35 U.S.C. 102(b) as anticipated by Bourne and Henrissat, is rendered moot. However, Applicants arguments are addressed below insofar as they may be applicable to newly added claims rejected herein under Bourne and Henrissat. Applicants argue in REMARKS filed 5/26/2009 that the art rejections are based on an incorrect construction of the claims, and point to Applicants explanation above in the response to the written description rejection. Applicants argue that "the claim construction provided in the Office Action is unreasonable and contrary to how this phrase would be interpreted by persons skilled in the art", noting that "under the Office's interpretation, almost all sequences are 100% identical". Applicants further argue that:

Bourne et al. and Levy et al. disclose carbohydrate-binding modules from various enzymes. However, neither reference disclose a carbohydrate-binding module which (a) has a sequence which has at least 90% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2; (b) is encoded by a DNA sequence that hybridizes to the DNA sequence of nucleotides 109-531 of SEQ ID NO: 1 under high stringency conditions; or (c) is a fragment of the sequence of amino acids 34-174 of SEQ ID NO: 2, as claimed herein.

Applicants traverse is not found persuasive for reasons of record as restated above. Particularly, Applicants argument that the claims construction is not correct because Applicants argue that the claim interpretation is overly broad regarding claim language drawn to, for example, "a polypeptide having a sequence which has at least

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90% identity with the sequence of amino acids 34-174 of SEQ ID NO:2" which Examiner interprets as a polypeptide having "a sequence", such as any di-peptide, or tri-peptide sequence, which has at least 90% identity found within the sequence of amino acids 34-174 of SEQ ID NO:2, is not persuasive because claims must be given their broadest reasonable interpretation during examination in light of the instant specification.

Newly added Claims 48-59 and 63-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy and Shoseyov in "Cellulose-binding domains Biotechnological applications" (Biotechnology Advances, 2002, Vol. 20;pp 191-213, made of record in the IDS). **This is a new rejection necessitated by claim amendments, however Applicants response to the previous rejection under 102(b) as being anticipated by Levy et al is addressed below.**

Claims 48-58 and 63-72 are as described above. Claim 59 is directed to detergent compositions comprising the CMB of claim 48 and a surfactant. Claim 73 is directed to a detergent composition comprising an enzyme hybrid of claim 64 and a surfactant.

Levy and Shoseyov teach carbohydrate-binding modules that are polypeptides that inherently comprise the dipeptides glycine-glycine, serine-serine, and/or alanine-valine. For example, Levy and Shoseyov teach cellulases and endo-beta-1,4-glucanases that contain CBDs and contemplate hybrid enzymes or fusion proteins (e.g.

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page 192 and 194, Figure 1 and legend). Levy and Shoseyov teach combining CBD's in detergent compositions (e.g. page 197, paragraph 1, lines 1-4).

Therefore, Levy and Shoseyov anticipate all the limitations of Claims 48-59.

Applicants response is to traverse the rejection and to cancel the rejected claims. Since Applicants have cancelled Claims 29-39 and 43-44, Applicants traverse of the rejection of Claims 29-39 and 43-44 under 35 U.S.C. 102(b) as anticipated by Levy et al, is rendered moot. However, Applicants arguments are addressed below insofar as they may be applicable to newly added claims rejected herein under Levy et al. Applicants argue in REMARKS filed 5/26/2009 that the art rejections are based on an incorrect construction of the claims, and point to Applicants explanation above in the response to the written description rejection. Applicants argue that "the claim construction provided in the Office Action is unreasonable and contrary to how this phrase would be interpreted by persons skilled in the art", noting that "under the Office's interpretation, almost all sequences are 100% identical". Applicants further argue that:

Bourne et al. and Levy et al. disclose carbohydrate-binding modules from various enzymes. However, neither reference disclose a carbohydrate-binding module which (a) has a sequence which has at least 90% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2; (b) is encoded by a DNA sequence that hybridizes to the DNA sequence of nucleotides 109-531 of SEQ ID NO: 1 under high stringency conditions; or (c) is a fragment of the sequence of amino acids 34-174 of SEQ ID NO: 2, as claimed herein.

Applicants traverse is not found persuasive for reasons of record as restated above. Particularly, Applicants argument that the claims construction is not correct because Applicants argue that the claim interpretation is overly broad regarding claim language drawn to, for example, "a polypeptide having a sequence which has at least

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90% identity with the sequence of amino acids 34-174 of SEQ ID NO:2" which Examiner interprets as a polypeptide having "a sequence", such as any di-peptide, or tri-peptide sequence, which has at least 90% identity found within the sequence of amino acids 34-174 of SEQ ID NO:2, is not persuasive because claims must be given their broadest reasonable interpretation during examination in light of the instant specification.

State of the Art

An isolated carbohydrate-binding module consisting of a polypeptide consisting of amino acids 34-174 of SEQ ID NO: 2 and an isolated carbohydrate-binding module consisting of a polypeptide encoded by a DNA sequence consisting of nucleotides 109-531 of SEQ ID NO: 1 are free of the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catherine S. Hibbert
Examiner U1636

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1636